REMARKS

Claims 1-16 were present in the application when filed. In response to a restriction requirement, Applicants elected the invention of Group 4 (claim 6) and presented new claim 17. Claims 1-17 were pending with claims 1-5 and 7-17 withdrawn from consideration. In response to an Office Action dated February 28, 2005, claims 1-5 and 7-17 were canceled. Claim 6, therefore, remains pending in the application.

Rejection under 35 U.S.C. §112, second paragraph

Claim 6 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the previous Office Action characterizes the Sp17 designation as a laboratory designation the use of which renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct antigens. Arguments in Applicants' response dated June 28, 2005 were deemed not persuasive because 1) the claimed antigen is not limited to the Sp17 of Lea et al.; the reference(s) disclosed in the specification are not incorporated by reference; and therefore, 3) that the information in the Lea et al. reference that might unambiguously define the claimed antigen would be considered new matter if the specification were amended to contain that information.

Preliminarily, the Examiner is directed to the first paragraph of the Background of the Invention section of the application (page 1, lines 21-27), which reads as follows:

> "Throughout this application various publications are referenced, many in parenthesis. Full citations for each of these publications are provided at the end of the Detailed Description and throughout the Detailed Description. ***The disclosures of each of these publications in their entireties are hereby incorporationed by reference in this application.***"

Additionally, Lea et al. (***Biochimica et Biophysica Acta***, 1307:263-266, 1996) as well as several other publications related to Sp17 are cited in the list of references on page 25 of the application; the disclosures of these references are properly incorporated by reference and are therefore, part of the disclosure of the present application.

As is well known in the art, sperm protein 17 (Sp17) is a highly conserved (61% homology among the protein sequences of mouse, rabbit, and human and 97% homology between human and baboon) mammalian protein ordinarily present on acrosome-reacted sperm.

Lea et al. states that Sp17 was first described in rabbit and was subsequently shown to be expressed in mouse. Lea et al. reports on the cloning and sequencing of human sperm protein, often referred to as HSp17. Although originally identified as a testis-specific antigen, Applicants have since discovered that multiple myeloma cells also express Sp17, making the protein one of a growing number of cancer/testis (CT) antigens which may be useful in immune targeting.

Sp17 is not unlike hundreds of other cell surface proteins that have been identified, extensively characterized and named in accordance with standard nomenclature conventions. The nomenclature frequently consists of an alphanumeric designation based on tissue of origin and molecular weight or chromosome location. In the present case, "Sp" signifies the tissue of origin, sperm, and "17" relates to the proteins approximate molecular weight.

The amino acid sequence of several orthologues of Sp17 are known, including, mouse, rabbit, baboon and human. Though polymorphisms may exist across species or within populations, one of skill in the art would immediately recognize that a protein designated as Sp17 unambiguously refers to a tissue-specific antigen having a known amino acid sequence.

For clarification purposes, claim 6 is amended above and the abbreviation, "Sp17" is replaced with the full protein name, "sperm protein 17."

In view of the above amendment, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejection under 35 U.S.C. §103

Claim 6 is rejected under 35 U.S.C. §103(a) as being anticipated by Chiriva-Internati et al. (***Blood***, 2000, 96:272b) in view of Lefkovits, ***Immunology Methods Manual. The Compreshensive Sourcebook of Techniques, Vol. 3, 1997, pages 1670-1673***. Specifically, the Office Action urges that it would have been *prima facie* obvious to one of skill in the art to make, using the technique taught by Lefkovits, an isolated cytotoxic T cell that specifically recognizes Sp-17 as taught by Chiriva-Internati et al.

Submitted herewith is a Declaration of the inventors under 37 CFR §1.131 that the inventors, in fact, are the authors of the Chiriva-Internati et al. reference cited by the Office Action (***Blood*** 96:272b, 2000), and that the provisional application from which the present application claims priority was filed within one year of the publication of the ***Blood*** article. The reference is therefore unavailable as prior art.

Lefkovits teaches a method for the isolation and propagation of T-cells that are specific for myelin basic protein (MBP). Autoreactive $CD4^+$ cells with specificity for MBP are the underlying cause of experimental autoimmune encephalomyelitis (EAE), an experimental model of multiple sclerosis (MS). Significantly, the isolation method of Lefkovits is directed to the separation of $CD4^+$ MBP-specific cells (page 1671, section entitled "Principle of method"). Lefkovits, therefore, does not teach or fairly suggest a method for the production or isolation of $CD8^+$ cytotoxic T cells specific for Sp17, does not teach the cells themselves or even the desirability of obtaining such cells. Given the unavailability of the teachings of Chiriva-Internati et al. as the inventors' own work, a prima facie case of obviousness cannot be made. Withdrawal of the rejection is respectfully requested.

For the foregoing reasons, claim 6 is believed in condition for allowance and such action is respectfully requested. Should the Examiner require clarification of any of the above, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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